AUG - 2 2001

K012085

Thermo Respiratory Group SENSORMEDICS

SomnoStar α Series Sleep System – Summary of Safety and Effectiveness

Submitter:

SensorMedics Corporation
22705 Savi Ranch Parkway
Yorba Linda, CA 92887
714-283-2228

Date Prepared:

August 1, 2001

Contact:

Earl Draper

Proprietary Name:

SomnoStar α Series Sleep System

Common Name:

Sleep Analysis System

Classification Name:

Device, Sleep Assessment

Intended Use:

The SomnoStar α Series Sleep System is intended to assist the user in diagnosing patients with sleep disorders by collecting physiological data from a sleeping patient, assisting the user in performing analysis of sleep data, and printing a hard-copy report of these data.

Device Description:

The SomnoStar α Sleep System receive input from bio-physical amplifiers, analyze these data according to software programs designed for use on computer systems included in the system configuration and output data in the form of reports generated by the printer option to the systems. Various components of the systems can be designed into already-existing sleep laboratories. A more detailed description is contained in the Operator's Manual.

Clinical and Non-Clinical Tests of Equivalency:

The SensorMedics SomnoStar α Series Sleep System is equivalent to the SensorMedics 4000 Series Sleep System distributed under 510(k) K915856. The primary difference is the inclusion of a different, optional bio-physical amplifier, the Cephalo Pro, to replace either the AmpStar or Dynagraph II bio-physical amplifiers. Because there are no performance differences caused by using the Cephalo Pro, no additional clinical or non-clinical tests were performed or submitted in the premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Larry Murdock
Vice President of Marketing
SensorMedics Corporation
22705 Savi Ranch Parkway
Yorba Linda, California 92887

APR - 9 2002

Re: K012085
Trade/Device Name: SomnoStar Alpha Series Sleep System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLV
Dated (Date on orig SE ltr): July 2, 2001
Received (Date on orig SE ltr): July 3, 2001

Dear Mr. Murdock:

This letter corrects our substantially equivalent letter of August 2, 2001.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Keosia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012085

Device Name: SomnoStar α (Alpha) Series Sleep System

Indications For Use:

The SomnoStar α Series Sleep System is indicated for use to assist the user(s) in diagnosing patients with sleep disorders; by collecting physiological data from a sleeping patient, assisting the user(s) in performing analysis of sleep data and printing a hard copy of these data. The data is collected, staged and scored with a computer-assisted program.

In use, the SomnoStar α Series Sleep System receives input from optional biophysical amplifiers, up to 32 channels in each, which is converted from analog to digital data and stored in a computer storage medium.

The SomnoStar α Series Sleep System is not intended to be used alone or in combination with another product as a life support device, a life support system, or as a critical component to a life support device or system. We do not claim compatibility with diagnostic imaging equipment.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012085

Prescription Use ✓ OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)